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PATENT APPLICATION
SERIAL NO. 10/777,514

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
ON APPEAL FROM THE EXAMINER TO THE BOARD
OF PATENT APPEALS AND INTERFERENCES**

In re Application of: Kerry Zang
Serial No.: 10/777,514
Filing Date: February 11, 2004
Group Art Unit: 3738
Examiner: Cheryl L. Miller
Confirmation No. 5263
Title: CONICAL, THREADED SUBTALAR IMPLANT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

REPLY BRIEF

Pursuant to 37 C.F.R. § 1.193, Appellants respectfully file this Reply Brief in response to the Examiner's Answer dated June 24, 2010 ("*Examiner's Answer*").

As explained in more detail below, the Examiner's final rejections of these claims cannot be properly maintained. Appellants respectfully request the Board to reverse these final rejections and instruct the Examiner to issue a Notice of Allowance with respect to these claims.

ARGUMENT

The *Examiner's Answer* consists of arguments presented in the Final Office Action dated 11/04/2010 ("*Office Action*"), along with a section responding to Appellants' arguments presented in the Appeal Brief dated May 26, 2010 ("*Appeal Brief*"). To reduce the burden on the Board, Appellants specifically address only the section of the *Examiner's*

Answer directed to Appellants' arguments in the *Appeal Brief*. The remaining portions of the *Examiner's Answer* have already been addressed in the *Appeal Brief*.

Objections to Specification

I. The Examiner's objection to the Specification is appealable pursuant to MPEP 608.04(c).

Previously, in the *Office Action*, the Examiner objected to the Specification under 35 U.S.C. § 132 as allegedly containing new matter. Specifically, the Examiner argued "[t]he amendment filed April 28, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. . . . The added material which is not supported by the original disclosure is as follows: each new recitation of substantially. Although applicant appears to have support for a constant thread height and pitch, applicant does not appear to have support for the term 'substantially' constant." See *Office Action*, page 2, lines 6-11. The Examiner also rejected Claims 40-44, 46-57, 62-63, and 65-72 under 35 U.S.C. § 112, first paragraph, stating "applicant does not have support for the term 'substantially' which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions." See *Office Action*, page 3, lines 3-5.

In the *Examiner's Answer*, the Examiner refused to consider Appellants' arguments directed to the above-described objection. Particularly, the Examiner stated, "[t]his objection has not been maintained in this examiners answer and has not been addressed herein as objections are not appealable unless by petition, see MPEP 706.01." See *Examiner's Answer*, page 7, lines 16-18. Appellants disagree.

MPEP 608.04(c) ***directly instructs*** Appellants to appeal objections to the specification under the above-referenced set of facts. According to that passage of the M.P.E.P.:

Where the new matter is confined to amendments to the specification, review of the examiner's requirement for cancelation is by way of petition. But ***where the alleged new matter is introduced into or affects the claims, thus necessitating their rejection on this ground, the question becomes an appealable one, and should not be considered on petition even though that new matter has been introduced into the specification also.***

See MPEP 608.04(c) (emphasis added). In this case, the Examiner rejected the claims under §112 and objected to the specification under §132, both for inclusion of the term "substantially." Thus, in this scenario the Examiner's objection has become and appealable rather than petitionable question. Appellants also contend that Appellants have not

introduced new matter into the Specification for the reason explained in their Appeal Brief and for the reasons explained below with respect to the §112 rejection of Claims 40-44, 46-57, 62-63, and 65-72.

Section 112 Rejections

I. Claims 40-44, 46-57, 62-63, and 65-72 comply with 35 U.S.C. § 112, first paragraph.

The Examiner rejects Claims 40-44, 46-57, 62-63, and 65-72 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Appellants respectfully traverse those rejections for the reasons stated below.

With respect to Claims 40-44, 46-57, 62-63, and 65-72, the Examiner asserts “[a]lthough appellant seems to have support for a constant thread height or pitch (support provided in original claim by appellant in response), appellant does not have support for the term “*substantially*” which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions.” See *Examiner’s Answer*, page 4, lines 2-5. Appellants respectfully disagree.

The Federal Circuit has construed numerous claim terms including the term “substantially.” See e.g., *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022 (Fed.Cir. 2002) (construing the terms “substantially constant” and “substantially below”); *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408 (Fed.Cir. 2000) (construing the term “substantially inward”); *York Prods., Inc. v. Cent. Tractor Farm & Family Ctr.*, 99 F.3d 1568 (Fed. Cir.1996) (construing the term “substantially the entire height thereof”); *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558 (Fed.Cir. 1996) (construing the term “substantially in the common plane”). Moreover, the term “substantially” does not need to be explicitly described in the specification in order to be supported. See e.g., *Deering Precision Instruments, L.L.C. v. Vector Distribution Systems, Inc.*, 347 F.3d 1314, 1323 (Fed. Dir. 2003) (construing term “substantially in an imaginary plane” even though “[a]s is often the case, the written description [did] not explicitly identify the meaning of the term ‘substantially.’”)

In *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819, 821-22, (Fed. Cir. 1988) the court explained that “usages such as ‘substantially equal’ and ‘closely approximate’ may serve to describe the invention with precision appropriate to the technology *and without*

intruding on the prior art.” (emphasis added). The Federal Circuit has further explained that “expressions such as ‘substantially’ are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to secure the invention. Such usage may well satisfy the charge to ‘particularly point out and distinctly claim’ the invention, 35 U.S.C. § 112, and indeed may be necessary in order to provide the inventor with the benefit of his invention. The court again explained in *Ecolab Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367, (Fed. Cir. 2001) that “like the term ‘about,’ the term ‘substantially’ is a descriptive term commonly used in patent claims to ‘avoid a strict numerical boundary to the specified parameter.’” (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)). Consequently, “[m]athematical precision should not be imposed for its own sake; a patentee has the right to claim the invention in terms that would be understood by persons of skill in the field of the invention.” *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1557 (Fed.Cir.1996), abrogated on other grounds.

In light of the well established acceptance of the term “substantially” to properly protect a patentee’s invention, Appellants respectfully contend one of ordinary skill in the art would appreciate Appellants’ specification supports “substantially constant” physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances that are inherent in mechanical devices. This is consistent with the MPEP which states “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a). Moreover, Appellants’ Specification explicitly states “[i]n certain other embodiments, thread height 54 is approximately 0.041 inches.” See Claim 16 as originally filed (“the thread height of each of the one or more threads is 0.041 inches”). Consequently, Appellants respectfully request the Board to withdraw the associated rejections of Claims 40-44, 46-57, 62-63, and 65-72, under 35 U.S.C. § 112, first paragraph.

Section 102 Rejections

The Examiner, under 35 U.S.C. § 102(b), rejects as allegedly being anticipated: Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 by U.S. Patent No. 5,951,560 to

Simon et al. ("*Simon*"), Claims 40, 55, and 70-72 by U.S. Patent No. 3,726,180 to Rosan, Sr. ("*Rosan*"), and Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 by U.S. Patent Publication No. 2002/0038123 A1 by Visotsky et al. ("*Visotsky*"). The Examiner, under 35 U.S.C. § 102(e), further rejects Claims 40-42, 44, 50, 52-57, 63, 66, 70, and 72 as allegedly being anticipated by U.S. Patent No. 7,608,105 B2 to Pavlov ("*Pavlov*"). See *Office Action*, pages 3-5.

I. Claims 40-42, 44, 47, 50, 52-57, 62, 63, 66, and 70-72 are patentable under 35 U.S.C. § 102(b) over *Simon*.

a. *Simon* fails to disclose a "substantially constant thread height" as recited in Claims 40, 44, 55, and 70.

In the *Examiner's Answer*, the Examiner continues to argue that Appellants' claims are directed to tapered configurations as shown in Figures 1a and 1b:

As only one thread height is disclosed with regards to fig. 1a, 1b, we must assume the figures intend to show a constant thread height and that the figures are not to scale (figs seem to show a slight taper, however spec discloses otherwise). Thus, "substantially" constant is believed by the examiner to not be supported (only constant is), and by allowing "substantially" constant into the claims, this broadens appellants original coverage to tapers as shown in appellants not to scale drawings.

See *Examiner's Answer*, page 8 lines 8-13. However, Appellants claims explicitly indicate that the claimed thread height is "substantially constant," not tapered. Appellants' specification includes support for both tapered (see e.g., Figures 1a and 1b) and substantially constant (see e.g., originally filed claims) thread heights.

Simon fails to disclose a "substantially constant" thread height. See *Examiner's Answer* page 8 (admitting that the threads shown in *Simon* are tapered). For at least those reasons Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Simon*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Simon*.

II. Claims 40-42, 44, 50, 52-57, 63, 66, 70 are patentable under 35 U.S.C. § 102(e) over *Pavlov*.

a. ***Pavlov*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claims 40, 44, 55, and 70.**

In the *Examiner’s Answer*, the Examiner continues to argue that *Pavlov* discloses the “at least one continuous and uninterrupted thread including . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” claimed by Appellants. In particular, the Examiner argues:

Thus the “at least one” in the claim is defined as one or more and in *Pavlov*’s case, pertains to 8 individual threads, each one of the 8 thread is individually uninterrupted and the at least one (8 threads) also span the full length of the body (the collection spans the entire length).

See *Examiner’s Answer*, page 9 lines 19-22. However, none of the threads allegedly disclosed in *Pavlov* spans “from the first end to the second end” as recited by Claim 40. Moreover, *Pavlov*’s threads cannot be collectively considered as the “at least one continuous and uninterrupted thread” claimed by Appellants because there are interruptions between each alleged thread of *Pavlov*. For at least those reasons, Appellants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Pavlov*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Pavlov*.

III. Claims 40, 55, and 70-72 under 35 U.S.C. § 102(b) are patentable under 35 U.S.C. § 102(b) over *Rosan*.

a. ***Rosan*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claims 40, 55, and 70.**

In the *Examiner’s Answer*, the Examiner maintains the rejection based on *Rosan* by arguing that the “annular groove” of *Rosan* represents the end of the alleged body of *Rosan*:

The appellant argues that thread 12 does not extend to each end of the body, is instead cut short by groove 15. The examiner disagrees. . . . Groove 15 is still considered part of the second end of the body, thus the thread 12 is considered by the examiner to span the length from the first to second end.

See *Examiner’s Answer*, page 9 lines 12-21. However, *Rosan* explicitly shows that a “pilot means 14” resides on the other side of “annular groove 15,” opposite threads 12. See Figure

1 (showing pilot means 14 residing on the opposite side of groove 15 from thread 12c; see also *Rosan* Col. 2 lines 42-45 (stating “[s]ituated between the lead thread 12c and pilot means 14 is an annular groove 15 which is formed by the bottom surface and top surface of said lead thread 12c and pilot means 14, respectively.”). Thus, annular groove 15 is not the end of the alleged body of *Rosan*.

Since the alleged thread of *Rosan* ends at the “annular groove 15” that separates thread 12c from the pilot means 14 located at the end of the alleged implant of *Rosan*, *Rosan* fails to disclose “at least one continuous and uninterrupted thread including . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claim 40. For at least those reasons, Appellants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Rosan*. For analogous reasons, independent Claims 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Rosan*.

IV. Claims 40-44, 47, 50, 52-57, 62-63, 66, 70, and 72 are patentable under 35 U.S.C. § 102(b) over *Visotsky*.

a. *Visotsky*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claims 40, 44, 55, and 70.

In the *Examiner’s Answer*, the Examiner continues to argue that *Visotsky* discloses the “at least one continuous and uninterrupted thread including . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” claimed by Appellants. In particular, the Examiner argues:

Thus the “at least one” in the claim is defined as one or more and in *Visotsky* case, pertains to 22 individual threads, each one of the 22 threads is individually uninterrupted and the at least one (22 threads) also span the full length of the body (the collection spans the entire length).

See *Examiner’s Answer*, page 11 lines 9-12. However, none of the threads allegedly disclosed in *Visotsky* spans “from the first end to the second end” as recited by Claim 40. Moreover, *Visotsky*’s threads cannot be collectively considered as the “at least one continuous and uninterrupted thread” claimed by Appellants because there are interruptions between each alleged thread of *Visotsky*. For at least those reasons, Appellants respectfully

contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Visotsky*. For analogous reasons, independent Claims 44, 55, and 70 and each of their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Visotsky*.

V. Claim 72 is patentable under 35 U.S.C. § 102(b) over *Simon*.

a. *Simon* fails to disclose “the direction of incline of the leading flank is equal and opposite to the direction of incline of the trailing flank” as recited in Claim 72.

In the *Examiner's Answer*, the Examiner argues that *Simon* discloses “the direction of incline of the leading flank is equal and opposite to the direction of incline of the trailing flank” as claimed by Appellants. In particular, the Examiner relies on surface 17 and buttress 18 illustrated in Figure 5 of *Simon*. See *Office Action*, page 4 lines 4-5. However, as *Simon* expressly shows, the direction of incline of surface 17 is not equal and opposite to the direction of incline of buttress 18. See e.g., Figure 5. For at least those reasons, Appellants respectfully contend that Claim 72 is allowable over *Simon*.

Section 103 Rejections

The Examiner, under 35 U.S.C. § 103(a), rejects Claims 67-69 as allegedly being unpatentable over *Visotsky* in view of the knowledge of one of ordinary skill in the art. See *Office Action*, pages 5-6.

I. Claim 67 and its respective dependent Claims are patentable under 35 U.S.C. § 103 over *Visotsky*.

a. *Visotsky*, fails to disclose a “continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claim 67.

As explained above with respect to the § 102(b) rejection of Claim 40 over *Visotsky*, *Visotsky* fails to disclose, “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end.” For at least those reasons, Appellants respectfully contend that Claim 67 and its dependent claims (e.g., Claims 68-69) are in condition for allowance.

II. Claim 69 is patentable under 35 U.S.C. § 103 over *Visotsky*.

a. *Visotsky* does not disclose, teach, or suggest that “the entirety of the medical device is inserted into the sinus tarsi” as recited in Claim 69.

Claim 69 is directed to “[t]he method of Claim 67, wherein the entirety of the medical device is inserted into the sinus tarsi.” In the *Examiner’s Answer*, the Examiner continues to rely on *Visotsky* to reject those limitations. However, *Visotsky* does not disclose that the entirety of its alleged medical device is inserted into the sinus tarsi. Rather, *Visotsky* explains that its medical device is only *partially* (not fully) inserted *into a fracture* (not the sinus tarsi) and the remainder of the device is cut away. See e.g., *Visotsky*, paragraph [0008]. Respectfully, *Visotsky’s* method step of partially placing a medical implant into a fracture site does not disclose, teach, or suggest a method step as claimed in Claim 69 wherein “the entirety of the medical device is inserted into the sinus tarsi.” For at least those reasons, Appellants respectfully contend that Claim 69 is in condition for allowance.

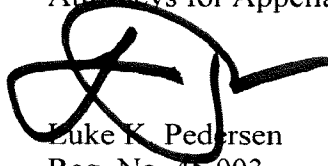
CONCLUSION

Appellants have demonstrated that the present invention, as claimed, is clearly distinguishable over the prior art cited by the Examiner. Therefore, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the Examiner's final rejection of the pending claims and instruct the Examiner to issue a notice of allowance of all pending claims.

Appellants believe no fee is due; however the Commissioner is authorized to charge any fees or credits to **Deposit Account No. 02-0384 of Baker Botts L.L.P.**

Respectfully submitted,

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